Northern Ireland Blood Transfusion Service	STANDARD OPERATING PROCEDURE (Operational Copy)

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Document Title: TO RUN A SESSION USING ELLAB TS PRO PROBES

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Department: REGULATORY AFFAIRS & COMPLIANCE DEPARTMENT

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CROSS REFERENCES

This SOP refers to the following documents:

Doc. Type	Doc. No.	Title
SOP	VL:015	Administration and Maintenance of Ellab Thermal Monitoring Equipment
SOP	VL:017	Result retrieval and analysis using Ellab Probe Data
FORM	DD:863	Temperature Mapping in Progress Form
NA		Ellab ValSuite User Manual

Key Change from Previous Revision:
Minor changes only.

1 RESPONSIBILITY

1.1 Validation Officer/BMS/RA&C Compliance Officer

2 INTRODUCTION

2.1 GENERAL

NIBTS purchased a temperature mapping system for use throughout the Service, to provide 'in-house' thermal mapping and permit full compliance with the current regulations.

The system purchased by NIBTS consists of a Master module and one Slave module each with four TS Pro logger slots, which would allow 8 loggers to be read at one time, however a session can control more than 100 loggers. The loggers are not linked to a specific position on the master or slave modules therefore a logger can be started in position A and read in position B. It is possible to run many different sessions at the same time, limited only by the loggers and sensors available.

This SOP explains how to use the Ellab equipment and software to run a temperature mapping session. Information on administrative features and maintenance of the Ellab equipment is in SOP:VL:015 'Administration and Maintenance of Ellab Thermal Monitoring System'. Data analysis of results obtained is found in SOP:VL:017 'Result Retrieval & Analysis of Ellab Probe Data'.

2.2 CLINICAL RELEVANCE/ PURPOSE OF EXAMINATION

2.2.1 Temperature Mapping is a requirement of GMP

2.3 PRINCIPLE OF EXAMINATION

2.3.1 Ellab temperature/RH probes are used to record temperature/RH and are placed in the area to be temperature/RH mapped according to a pre-defined unit configuration.

3 HAZARD AND SAFETY PRECAUTIONS

3.1 The use of Ellab TS Pro Probes poses no significant health and safety risk.

4 MATERIALS

4.1 EQUIPMENT AND SPECIAL SUPPLIES

4.1.1   PC/ Computer system with ValSuite Pro software
4.1.2   Ellab TrackSense Pro X Data Logger
4.1.3   Ellab Single Rigid Temperature Sensors
4.1.4   Ellab Single Flexible Teflon Sensors
4.1.5   Ellab RH ($\pm$ 2%) with internal temperature sensors
4.1.6   Ellab Multi TrackSense Pro reader station
4.1.7   Ellab TrackSense Pro Slave reader station
4.1.8   Colour Printer
4.1.9   Digital Camera
4.1.10 70% Alcohol wipes

4.2   SPECIMEN REQUIREMENTS AND MEANS OF IDENTIFICATION

Not Applicable.

4.3   REAGENTS, STANDARDS OR CALIBRANTS AND INTERNAL CONTROL MATERIALS

Not Applicable.

5   CALIBRATION

5.1   The Ellab probes are posted to the supplier Ellab for annual calibration or repair.

6   PROCEDURE

6.1   Preparing to start a TS Pro Session

6.1.1   It is important to attach any additional expansion modules to the Master Reader station before connecting the USB cable to the Master Reader and then to the PC.

6.1.2   Assemble the TrackSense (TS) Pro X loggers as described in SOP: VL:015 adding a suitable sensor.

6.1.3   Ellab TS Pro Sensor types available in NIBTS are:

Single Rigid Temperature Sensor
Single Flexible Teflon Temperature Sensor
Dual Temperature / RH (±2%) with an internal temperature Sensor

6.1.4   Log onto the ValSuite programme and enter your Username and Password.

6.1.5   Confirm the presence of the Reader icon with a GREEN cable in top right hand corner of the ValSuite screen.
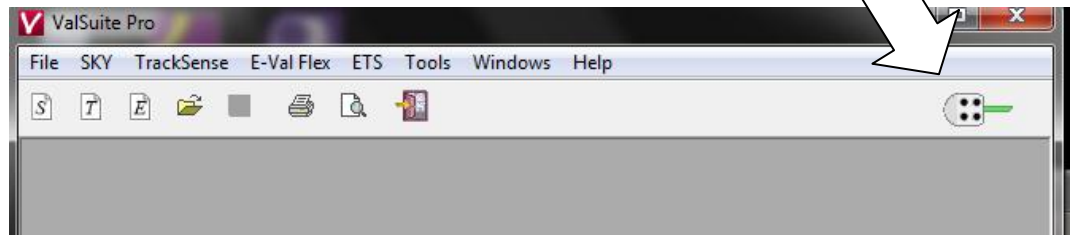
This icon confirms that the Reader Station is attached. If the icon is not there, connect the Reader Station to the PC.

6.1.6   Confirm the green power light on the reader station and place the loggers with sensors attached in the reader slots.
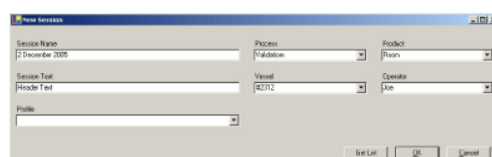
6.2   Starting the session

6.2.1   The start time and date is automatically noted in the session data. Each session must have a unique ID, it is impossible to restart a run or start a new session with the same ID.

6.2.2   There are a number of ways to start an Ellab session depending on the user's needs. In NIBTS the Quick Start and Delayed Unit start are the preferred options, others may be found in the Ellab User Manual.
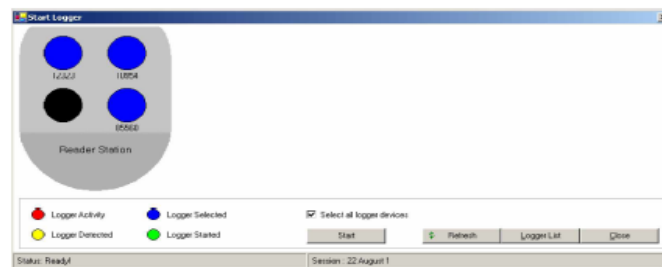
6.3   Quick Start

6.3.1   The Quick Start option is the most direct and the fastest way to start a session.

6.3.2   The session can be started either by placing loggers in the reader station and clicking **File**, **New**, **TrackSense Session**, or **TrackSense**, **Start Logger**, or by clicking the TrackSense 'T' icon.

The New Session dialog box opens.

6.3.3   Enter the session information into the fields.

6.3.4   Click '**OK'** the application window opens.

Click on the **Tracksense** icon in the ValSuite toolbar and select **Start Logger**. The loggers can be started this way without a specified unit configuration. It is possible to start the loggers immediately or to delay the start by clicking on **Logger Settings**.

N.B Normally in NIBTS the unit configuration specific to the area to be mapped is added to the session. This unit has a predefined number of loggers and positions for a specific area/equipment. The unit numbers can be found on the mapping by month list on the Mapping Information Board in RA&C department.

To add a unit, highlight the session name, right click, select add unit;

a window opens with a list of units, highlight the correct one for the area to be mapped and click on Ok

The unit is added to the session

To start the loggers. Click on '**TrackSense**' ⬚ in the ValSuite toolbar, select **Logger Start** and the **Start Logger** dialog box opens.

6.3.5   Select the loggers to be started or checkmark '**Select all logger devices'.**

6.3.6   Right Click on the logger position and select '**Logger Settings'**. Or **Click** the '**Logger Settings'** button at bottom right of 'Start Logger' dialogue box.
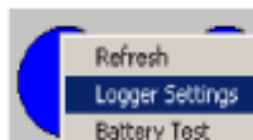
6.3.7   In Logger Settings each Sensor type has individual settings. Click the down arrow to choose a different sensor type. The dialog box lists the different sensor types present in the reader station.
NOTE: Multiple sensor types cannot be started simultaneously. If there is a need to use different sensor types in a session e.g. for NIBTS General Stores which has 2 dual RH temperature probes in the unit, you need to ensure the dual RH/temperature probes are placed in the reader block by themselves and check the unit logger positions are correct for the probes in the block at the time.
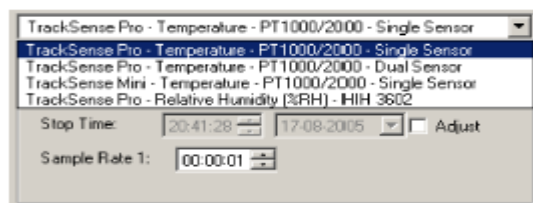
6.3.8   For Quick Start ensure the start and stop adjust boxes are blank.

Add a start time if a delayed start is required and click **Start**. If there are more than 8 loggers in the unit, place the first 8 started in a carrier box.

Set sample rate,
15mins for week long mappings
5 mins for 24 hour mappings
1 min for the Dometic freezers, mapping a run
Click 'OK'.

If more loggers need to be started for the same unit, then place them into the reader station, click the 'refresh' button, you will be asked to confirm that you wish to do this. Repeat the logger settings as all loggers started for a unit must have the same logger settings applied. After all loggers have been started, click '**Close'** to close the Start Logger dialog box.

6.3.9 Print out the unit configuration and use it to place the started loggers according to the unit configuration in the area to be mapped. Make a note on this print-out where the REES/Comark, continuous temperature monitoring probe/s are positioned.

6.3.10 Clean loggers with 70%Alcohol wipes, place as unit configuration in area to be mapped along with notices as appropriate. Also place a completed DD:863 Temperature Mapping in Progress form on the access points to the area being mapped so that door openings/ activity in the area is logged.

6.3.11 Place a form DD:863 Temperature Mapping in Progress form onto the front door of the chamber or area being mapped to indicate that a mapping session is in progress and to request that details of the time and duration of the door opening is documented.

N.B. Relative Humidity (RH) loggers measure RH and temperature at the same time e.g. If using 1 Ellab RH logger and wish to use position names in the unit configuration 2 positions names will have to be pre-assigned to the unit, 2 for each RH logger.

6.3.12 Check Loggers

Go to **TrackSense** and activate **Logger List**. This will list all active programmed loggers that you have started; you will not be able to see the loggers started on other PC's. Review detail to confirm they were programmed correctly.

6.4   Delayed Start using units

6.4.1   A delayed start is helpful for tests or studies that require a period of time for the loggers to equilibrate prior to collecting data, or if a start timeout is after hours or when a user isn't available to manually start the loggers. This is the most commonly used start option in NIBTS temperature and RH mapping.

6.4.2   There are equilibration times for each temperature range mapped during which the probes must be placed in the mapping positions
-80°C freezers equilibration time is 6 hours
-40°C freezers equilibration time is 4 hours

-20°C freezers equilibration time is 3 hours

2°C to 6°C, 8°C or 10°C fridge/cold room equilibration time is 3 hrs

Room Temperature Incubators/labs/stores equilibration time is 1.5 hrs

There is no equilibration time for the Dometic Freezers mappings NOTE the Dometic freezers mapping cannot use a delayed start so use a quick start with no defined start or stop times.

6.4.3   A Unit is a predefined program giving the probe positions descriptions and including a photograph or diagram showing where the probes are to be placed and the sample rate. In NIBTS a specific unit is created for each piece of equipment or area mapped and is saved for future use. Users performing the same study many times with the same configuration of loggers will want to use the Unit to save time, make the start up process much easier and to link the Position and the Sensor/Logger number when the probes are started.

6.4.4   The Unit by Position option is used in NIBTS. All defined units can be saved as templates and reloaded from the unit list in the toolbar and the loggers started. A loaded unit (a unit attached to a session) can be changed using the Edit function or removed using the Remove function prior to the probes being started. A Unit template can be created using sensor number if required instead of position.

6.4.5   To start a session using a unit, click **File**, **New**, and **TrackSense Session** or click on the TrackSense quick start icon.

6.4.6   The New Session dialog box opens

6.4.7   Session name box is completed with the name of the area being mapped. To the session text box is added the mapping number for this session. Profile is not currently used in NIBTS so add N/A. In the Process box choose the Temperature Mapping option or type.

6.4.8   Complete the session details. Click '**OK'**. The application window opens. Highlight the session name, **right click** and select '**Add Unit'**.
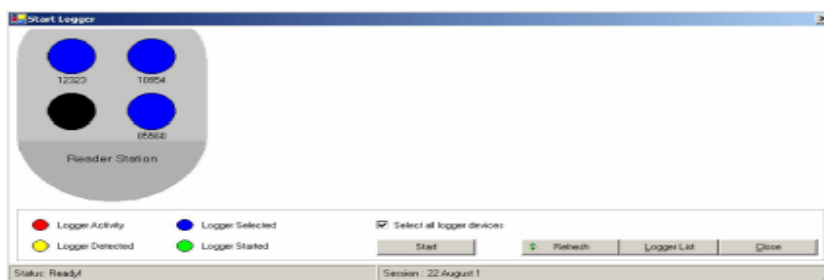

6.4.9   The Unit dialog box opens.

Highlight the unit to be selected and click '**OK'**. The unit is added to the session.

6.4.10 Place the loggers in the reader station and on the top bar click **TrackSense**, **Start Logger**.
The Start Logger dialog box opens.

6.4.11 Select the loggers to be started by clicking on them individually or checkmark '**Select all logger devices'.**

6.4.12 **Right Click** on the logger position and select '**Logger Settings'**. Or Click the '**Logger Settings**' button at bottom right of the '**Start Logger'** dialogue box.
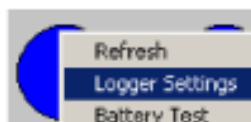
6.4.13 Each Sensor type has individual settings. Click the down arrow to choose a different sensor. The dialog box lists the different sensor types present in the reader station. NOTE: Multiple sensor types cannot be started simultaneously. If there is a need to use different sensor types in a session e.g. for NIBTS General Stores which has 2 dual RH temperature probes in the unit, you need to ensure the dual RH/temperature probes are placed in the reader block by themselves and check the unit logger positions are correct for the probes in the block at the time. Start the probes as required.
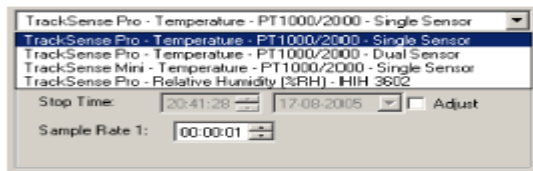
6.4.14   Click logger settings to start the probes or to set up a delayed start. For a delayed start, a start time, click the Start Time Adjust check box. Enter the required Start Time and do the same for the chosen Stop Time, and select a Sample Rate 1.
Sample rate for 24 hour mapping is 5 minutes (maximum)
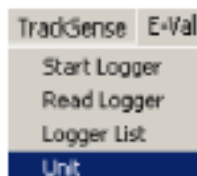Sample rate for a week long mapping is 15minutes (maximum)
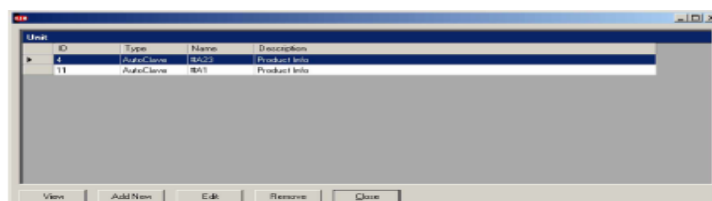Sample rate for the Dometic freezer mapping is 1minute (maximum)
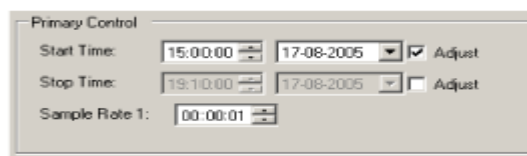
Continue as for 6.3.8

6.5   To Create a New Unit

6.5.1   Click TrackSense, select 'Unit.'

6.5.2   The Unit dialog box opens.

Click '**Add New'**.

6.5.3   The Unit can be configured according to **Unit Type**, **Unit Name, Unit Description, Placement Method, Position Name, Position Description, Sensor, Sample Rate**, and **Images**. There are predefined unit types present but it is also possible to type in the field.

6.5.4   Enter correct **Unit Type, Unit Name**, and **Unit Description** and select the **Placement Method**.

If **By Sensor Number** is selected, the sensor number field turns active.
If **By Position** is selected, the sensor number turns inactive.

NIBTS usually use Position Name as placement type. The **Position Name** can either be entered manually or selected from the **Pre-Defined Names** database using the small scroll down arrow or the position can be defined as 1,2,3 etc.

By Sensor Number: By Position:

Continue to add positions until all those required are identified and then add a probe position for beside the REES/Comark, continuous temperature monitoring probe/s and an ambient probe also occasionally a second ambient is required.

6.5.5   Click the **Images** button, the images box opens

Right click on the input area and select Load Bitmap. An Open dialog box opens.

Go to the Ellab folder on the 'I' drive to upload a picture or diagram specific for the unit.
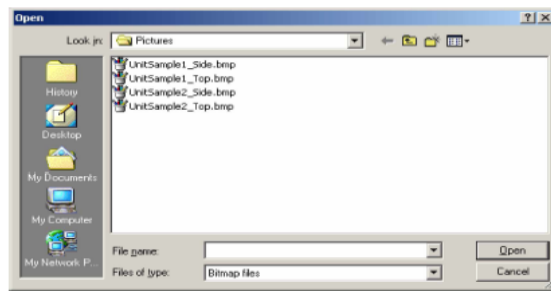
6.5.6   Diagrams of a side view and a top down view of the equipment or area being mapped are normally used. Select a picture and click **Open**. The image is added to the unit. A second image can also be added in the same way.
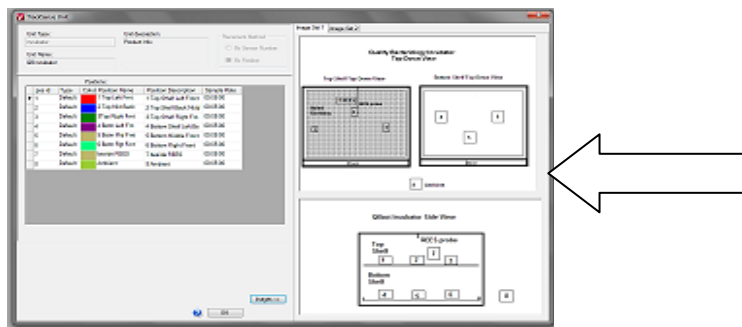

It may be necessary to right click on the added picture to resize it.

6.5.7   Highlight the first Position line, left click, and draw the cursor to the picture at the place where the logger should be positioned. Release the mouse button and the position number is marked using a yellow information box. The information box may define the position number or the sensor number.
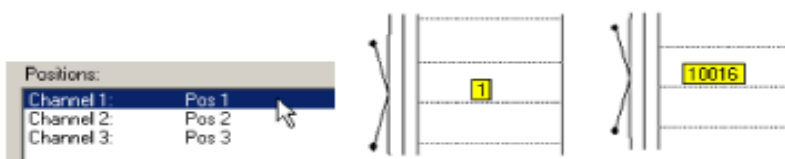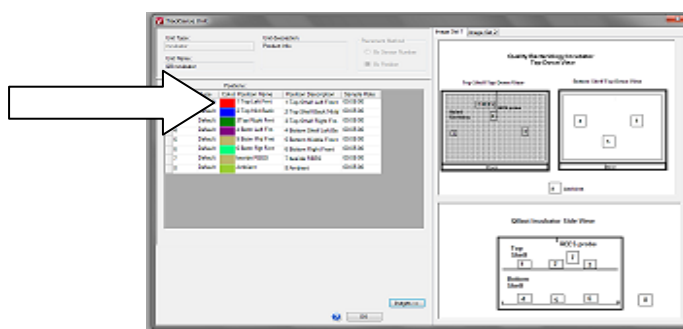
6.5.8   Continue until all the loggers positions are defined in the template. If the position of the yellow information box requires to be changed, double click on it, a 4 pointed arrow appears as the curser and allows the yellow

position box to be moved. To remove the yellow information box completely right click on it
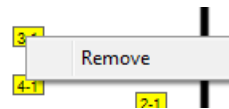
And then click on remove.

6.5.9 Click '**OK'** and '**Close'** to close the Unit dialog box. The unit will be saved for future use in the unit list and can be added to a session to define the probe positions in a mapping.

6.5.10 Start the loggers as described in 6.3.8. Close the Start Logger dialog box. Print out the unit configuration and use it to place the started, cleaned loggers according to the unit configuration in the area to be mapped.

6.5.11 The chamber or area being mapped will have a notice placed on it (FORM:DD:863) to indicate that a mapping session is in progress and to request that details of the time and duration of the door opening is documented.

6.6 Using Units

6.6.1 The TS Pro logger system can be started using the unit function. To start a session using a unit, click **File**, **New**, and **TrackSense Session** or click on the TrackSense quick start icon.


6.6.2 The New Session dialog box opens.

6.6.3 Session name box is completed with the name of the area being mapped. To the session text box is added the mapping number for this session. Profile is not currently used in NIBTS so add N/A. In the Process box choose the Temperature Mapping option or type.

Click **OK**. The application window opens. Highlight the session name and select **Add Unit**.
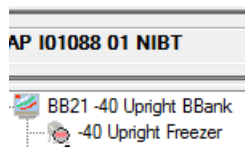
6.6.4   The Unit dialog box opens.
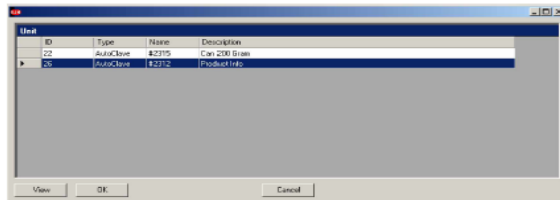
6.6.5   Each NIBTS area mapped has a mapping unit identified by a number. A list of units is recorded on the Mappings by Month sheet found on the mapping Information Board and in the Ellab folder on the 'I' drive.

6.6.6   Highlight the unit and click **OK**. Note the number of loggers required for the unit again this information is on the Mappings by Month Sheet or highlight the unit, right click and select view, to view the unit. Place the number of loggers required to be started beside the reader station so that the correct number of loggers will be started.

Place the loggers in the reader station and click **TrackSense**, **Start Logger**. To start the loggers. Click on '**TrackSense'** in the ValSuite toolbar, select Logger Start and the Start Logger dialog box opens.
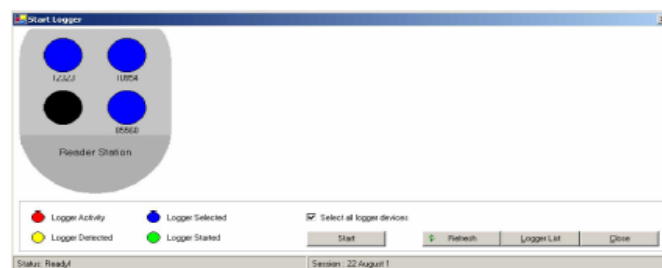

6.6.7   Select the loggers to be started or checkmark '**Select all logger devices'.**

6.6.8   Right Click on the logger position and select '**Logger Settings'**. Or **Click** the '**Logger Settings'** button at bottom right of 'Start Logger' dialogue box.

6.6.9   In Logger Settings each Sensor type has individual settings. Click the down arrow to choose a different sensor type. The dialog box lists the different sensor types present in the reader station.
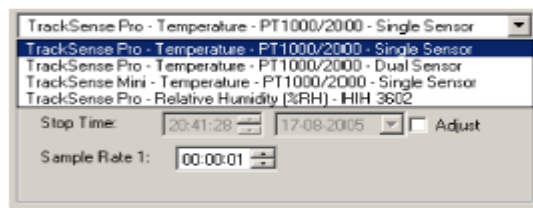
6.6.10 For Quick Start ensure the start and stop adjust boxes are blank.
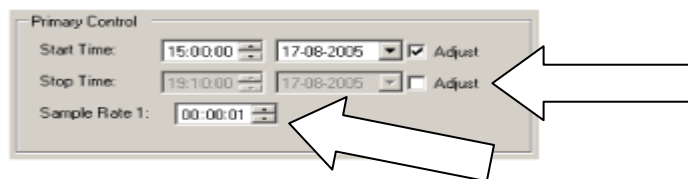
Add a start time if a delayed start is required and click **Start**. If there are more than 8 loggers in the unit, place the first 8 started in a carrier box.

Set sample rate,
15mins for week long mappings
5 mins for 24 hour mappings
1 min for the Dometic freezers, mapping a run
Click 'OK'.

If more loggers need to be started for the same unit, then place them into the reader station, click the 'refresh' button, you will be asked to confirm that you wish to do this. Repeat the logger settings as all loggers started for a unit must have the same logger settings applied. After all the loggers have been started click '**Close'** to close the Start Logger dialog box.

6.6.11 Print out the unit configuration and use it to place the started loggers according to the unit configuration in the area to be mapped. Make a note on   this print-out where the REES/Comark, continuous temperature monitoring probe/s are positioned. Clean loggers with 70% Alcohol wipes.

6.6.12 Place the loggers according to the unit configuration in the area to be mapped along with notices as appropriate. Also place a completed DD:863 Temperature Mapping in Progress form on the access points to the area being mapped so that door openings/ activity in the area is logged.

6.6.13 Place a form DD:863 Temperature Mapping in Progress form onto the front door of the chamber or area being mapped to indicate that a mapping session is in progress and to request that details of the time and duration of the door opening is documented.

N.B. Relative Humidity (RH) loggers measure RH and temperature at the same time e.g. If using 1 Ellab RH logger and wish to use position names in the unit configuration 2 positions names will have to be pre-assigned to the unit, 2 for each RH logger.

6.7   Check Loggers

6.7.1   Go to **TrackSense** and activate **Logger List**. This will list all active programmed loggers that you have started; you will not be able to see the loggers started on other PC's. Review detail to confirm they were programmed correctly.

6.8   To Read the TrackSense Pro Loggers

6.8.1   Once the application is complete, place the loggers in the reader station. Click, **TrackSense**, **Read Logger**. The Read Logger dialog box opens and scans the reader for loggers.
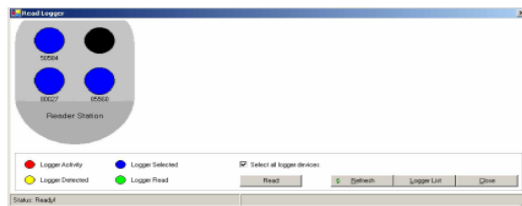
6.8.2   Click the '**Select all logger devices'** box. Click **Read** to read the selected loggers. Once the loggers are read, the graph appears in the application window. Click **Close** to close the Read Logger window.

6.9   Further Information on Ellab Probes and the Software

Further information on Ellab probes and the software used may be obtained from the ValSuite User Manual.

6.10   LIMITATIONS OF THE EXAMINATION

6.10.1   The Ellab probes can only be used by those trained in their use.

6.10.2   The Ellab probes must only be used within their calibration period

6.10.3   In the event the Ellab probes, reader station or ValSuite software did not work an external contractor would have to carry out temperature mapping until the mapping equipment was repaired or replaced

7   RESULTS

7.1   Data Analysis

Refer to SOP:VL:017 'Result Retrieval and Analysis of Ellab Probe Data'.